

REMARKS

Claims 1-18 are pending in this application. Claims 1, 3 and 11 have been amended. Specifically, independent claims 1 and 11 have been amended to make it clear that a "suture loop" is formed of a strand of suture. Although the term "suture loop," when read in light of the specification (paragraph [0024]), could only be reasonably interpreted as a loop formed of a strand of suture, claims 1 and 11 have been amended to avoid any ambiguity in this regard. Importantly, no new issue is raised by this clarifying amendment, and entry of the amendment is proper and is respectfully requested.

Claims 1, 3, 4 and 7 are rejected under 35 U.S.C. § 102(e) as being anticipated by Morgan et al. (U.S. Patent No. 6,666,877) ("Morgan"). This rejection is respectfully traversed.

The present invention, as recited in independent claim 1, is a "suture anchor" comprising "a bioabsorbable anchor body having a proximal end and a distal end" and "a suture loop formed of a strand of suture insert-molded into the bioabsorbable anchor body, the suture loop being disposed completely within the anchor body."

Morgan relates to a "suture anchor for securing soft tissue to bone, including a body having opposing first and second ends, a longitudinal axis extending between the ends, an external threaded portion extending from the first end, and a bore extending from the second end towards the first end." (Abstract). Morgan also teaches that the anchor additionally includes "an eyelet receivable within the first and the second pairs of slots of the body and having an opening for receiving a suture, and a spring biasing the eyelet into the bore." (Abstract).

Morgan does not anticipate the subject matter of claims 1, 3, 4 and 7. Morgan is silent about "a bioabsorbable anchor body" having "a suture loop formed of a strand of suture insert-molded into the bioabsorbable anchor body, the suture loop being disposed completely within the anchor body," as independent claim 1 recites. Morgan teaches that spring 32 (which is provided within the body 12 of suture anchor 10) is "attached with an eyelet 38 having an opening for receiving sutures." (Col. 4, ll. 9-10). Morgan also teaches that "eyelet 38 is preferably molded integrally with the spring 32" (col. 4, l. 11) and that spring 32 is a "helical tension spring 32." Morgan emphasizes that "the spring can comprise a simple elastic band or strip of elastically resilient material." (Col. 4, ll. 52-55). Thus, spring 32 and integrally molded eyelet 38 of Morgan (which would arguably correspond to the suture and "suture loop" of the claimed invention) are formed of an elastic material, and not of suture material, as in the claimed invention. Eyelet 38 of Morgan is not a "suture loop," much less a "suture loop formed of a strand of suture insert-molded into the bioabsorbable anchor body, the suture loop being disposed completely within the anchor body," as claim 1 recites. For at least these reasons, Morgan fails to anticipate the subject matter of claims 1, 3, 4 and 7, and withdrawal of the rejection of these claims is respectfully requested.

Claims 11, 13, 15 and 16 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Morgan in view of Grafton et al. (U.S. Patent No. 5,964,783) ("Grafton '783"). This rejection is respectfully traversed.

As noted, the claimed invention relates to a bioabsorbable suture anchor. Independent claim 11 recites an "insert-molded suture anchor" comprising "a bioabsorbable anchor body," "a drive socket" and "a suture loop disposed completely

within the drive socket of the bioabsorbable anchor body, the suture loop formed of a strand of suture insert-molded into the anchor body.”

Grafton '783 relates to an “insert-molded suture anchor having a biodegradable polymer body molded around a loop of suture.” (Abstract). Grafton '783 teaches that “[A] drive head disposed on the proximal end of the body, and a screw thread spirals around the body.” (Abstract).

The subject matter of claims 11, 13, 15 and 16 would not have been obvious over Morgan and Grafton '783, considered alone or in combination. Specifically, the Office Action fails to establish a *prima facie* case of obviousness. Courts have generally recognized that a showing of a *prima facie* case of obviousness necessitates three requirements: (i) some suggestion or motivation, either in the references themselves or in the knowledge of a person of ordinary skill in the art, to modify the reference or combine the reference teachings; (ii) a reasonable expectation of success; and (iii) the prior art references must teach or suggest all claim limitations. See e.g., In re Dembiczak, 175 F.3d 994 (Fed. Cir. 1999); In re Rouffet, 149 F.3d 1350, 1355 (Fed. Cir. 1998); Pro-Mold & Tool Co. v. Great Lakes Plastics, Inc., 75 F.3d 1568, 1573 (Fed. Cir. 1996).

In the present case, Morgan and Grafton '783, alone or in combination, do not disclose, teach or suggest the subject matter of claims 11, 13, 15 and 16. Morgan is silent about an “insert-molded suture anchor,” much less about an “insert-molded suture anchor” having “a bioabsorbable anchor body” and “a suture loop disposed completely within the drive socket of the anchor body, the suture loop being formed of a strand of suture insert-molded into the anchor body,” as claim 11 recites. As noted above, eyelet 38 of Morgan is not a “suture loop,” much less a “suture loop disposed completely within the

anchor body” and “formed of a strand of suture insert-molded into the anchor body,” as claim 11 recites.

Grafton '783 fails to rectify the deficiencies of Morgan. Grafton '783 does not disclose, teach or suggest “a bioabsorbable anchor body” with “a suture loop disposed completely within the drive socket of the anchor body,” as claim 11 recites. Loop 11 of Grafton '783 (which would arguably correspond to the “suture loop” of the claimed invention) is located outside the hexagonal drive head 10 and outside the body 4, and not “completely within the anchor body,” as in the claimed invention.

Applicants also submit that a person of ordinary skill in the art would not have been motivated to combine the teachings of Morgan with those of Grafton '783, to arrive at the claimed invention. Specifically, one skilled in the art would not have been motivated to “modify the device of Morgan by insert molding the suture loop to the anchor body in order to effectively secure the suture loop to the anchor body,” as the examiner asserts. (December 11, 2006 Office Action at 5). The crux of Morgan is a helical spring 32 that is adapted “to permit to expand and contract within the central longitudinal bore 24.” (Col. 4, ll. 5-7). In this manner, movement of spring 32 along the longitudinal axis of the anchor body allows eyelet 38 and the suture strand received therein to be “repositioned as needed during a surgical procedure without removing the suture anchor 10.” (Col. 4, 20-23). In contrast, the crux of Grafton '783 is an anchor having a fixed, non-movable suture that is insert-molded directly into the suture anchor during the manufacturing process. Thus, a person skilled in the art would not have been motivated to combine helical spring 32 of Morgan (which expands and contracts within the bore of the anchor) with the fixed insert-molded suture of Grafton '783.

In addition, Applicants note that courts have held that “[I]f the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious.” M.P.E.P. § 2143.01 (citing In re Ratti, 270 F.2d 810, 123 U.S.P.Q. 349 (CCPA 1959)). This is because the “suggested combination of references would require a substantial reconstruction and redesign of the elements shown in [the primary reference] as well as a change in the basic principle under which [the primary reference] construction was designed to operate.” In re Ratti, 270 F.2d at 813, 123 U.S.P.Q. at 352.

In the present case, employing the insert-molding technique of Grafton ‘783 *in lieu* of the fabrication process of Morgan, as the Office Action suggests, “would require a substantial *reconstruction* and *redesign* of the elements shown in [Morgan] (emphasis added).” Thus, the suggested combination of Grafton ‘783 and Morgan would have to eliminate the helical spring 32 and suture eyelet 38 of Morgan and the way the sutures are ultimately positioned relative to tissue during surgery and, thus, redesign and reconstruct the elements of Morgan. For at least these reasons, the Office Action fails to establish a *prima facie* case of obviousness, and withdrawal of the rejection of claims 11, 13, 15 and 16 is respectfully requested.

Claims 9, 10, 14, 17 and 18 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Morgan, or the combination of Morgan and Grafton ‘783 in view of Grafton et al. (U.S. Patent No. 6,319,270) (“Grafton ‘270”). This rejection is respectfully traversed.

The subject matter of claims 9, 10, 14, 17 and 18 would not have been obvious over Morgan, Grafton '783 and Grafton '270, whether considered alone or in combination. None of the cited references, alone or in combination, discloses, teaches or suggests all limitations of independent claims 1 and 11. Morgan, Grafton '783 and Grafton '270 do not disclose, teach or suggest "a bioabsorbable anchor body" with "a suture loop formed of a strand of suture insert-molded into the bioabsorbable anchor body," the suture loop being "disposed completely within the anchor body," as claims 1 and 11 recite. As noted above, Morgan and Grafton '783 do not disclose "a suture loop formed of a strand of suture insert-molded into the bioabsorbable anchor body, the suture loop being disposed completely within the anchor body." Grafton '270 teaches a headed bioabsorbable tissue anchor with a flat head for engaging tissue and continuous thread spiraling around a tapering central core. Grafton '270 does not even teach a suture loop, much less a suture loop having the characteristics recited in claims 1 and 11. For at least these reasons, the Office Action fails to establish a *prima facie* case of obviousness and withdrawal of the rejection of claims 9, 10, 14, 17 and 18 is respectfully requested.

Claims 9 and 17 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Morgan, or the combination of Morgan and Grafton '783, in view of Bidwell (U.S. Patent No. 74,489). This rejection is respectfully traversed.

Morgan, Grafton '783 and Bidwell, considered alone or in combination, do not disclose, teach or suggest all limitations of independent claims 1 and 11 and of dependent claims 9 and 17. As noted, Morgan and Grafton '783 do not disclose "a suture loop disposed completely within the anchor body." Bidwell fails to rectify the deficiencies of Morgan and Grafton '783. Bidwell teaches a "wood-screw which would penetrate wood

more readily," and none of the limitations of independent claims 1 and 11 and of dependent claims 9 and 17. For at least these reasons, the Office Action fails to establish a *prima facie* case of obviousness and withdrawal of the rejection of claims 9 and 17 is respectfully requested.

Claims 2 and 12 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Morgan, or the combination of Morgan and Grafton '783. This rejection is respectfully traversed.

Morgan and Grafton '783, considered alone or in combination, do not disclose, teach or suggest all limitations of independent claims 1 and 11 and of dependent claims 2 and 12. Neither Morgan nor Grafton '783 discloses, teaches or suggests "a suture loop formed of a strand of suture insert-molded into the bioabsorbable anchor body, the suture loop being disposed completely within the anchor body," as claims 1 and 11 recite. The Office Action fails to establish a *prima facie* case of obviousness and withdrawal of the rejection of claims 2 and 17 is respectfully requested.

Claims 5 and 6 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Morgan in view of Schmieding et al. (U.S. Patent No. 6,214,031). This rejection is respectfully traversed.

Neither Morgan nor Schmieding, considered alone or in combination, discloses, teaches or suggests the subject matter of claim 1 and of dependent claims 5 and 6. Morgan is silent about "a suture loop disposed completely within the anchor body," as claim 1 recites. Schmieding teaches a corkscrew suture anchor with "a continuous thread spiraling around a tapering central core," and not the limitations of independent claim 1

and of dependent claims 5 and 6. For at least these reasons, withdrawal of the rejection of claims 5 and 6 is respectfully requested.

Claim 8 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Morgan in view of Stahelin (U.S. Patent No. 5,695,497). This rejection is respectfully traversed.

Morgan and Stahelin, considered alone or in combination, do not disclose, teach or suggest all limitations of claim 1 and of dependent claim 8. Neither Morgan nor Stahelin discloses, teaches or suggests "a bioabsorbable anchor body" having "a suture loop formed of a strand of suture insert-molded into the bioabsorbable anchor body, the suture loop being disposed completely within the anchor body," as independent claim 1 recites. Stahelin teaches a screw made of biodegradable material and having a "coaxial channel of saw-toothed star-shaped transverse cross-sectional profile," and not a bioabsorbable anchor body with "a suture loop formed of a strand of suture insert-molded into the anchor body, the suture loop being disposed completely within the anchor body," as in the claimed invention. For at least these reasons, the Office Action fails to establish a *prima facie* case of obviousness and withdrawal of the rejection of claim 8 is also respectfully requested.

Allowance of all pending claims is solicited.

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